

**MEDICAL BOARD OF CALIFORNIA  
DEPARTMENT OF CONSUMER AFFAIRS**

**INITIAL STATEMENT OF REASONS**

**Hearing Date:** Friday, May 9, 2003

**Subject Matter of Proposed Regulations:** Standards and Methodology for the Review  
of International Medical Schools

**Sections Affected:** Title 16, Sections 1300.4 and 1314

**Specific Purpose of each adoption, amendment, or repeal:**

The specific purpose of amending Section 1300.4 is to add definitions for the terms that will be utilized in the regulatory language relating to the medical school review process. The purpose of adopting Section 1314.1 is to outline the standards and methodology that the Division of Licensing uses to review international medical schools in order to determine their compliance with Sections 2089 and 2089.5 of the Business and Professions Code.

**Factual Basis**

Section 2084 of the Business and Professions Code authorizes the Division of Licensing (hereinafter referred to as the Division) to approve medical schools that comply with the medical education requirements in Sections 2089 of the Code. Section 2089 requires medical schools to provide a curriculum of a certain length that includes training in the basic sciences and clinical sciences course areas listed in the section. Section 2089.5 further specifies the minimum length and content of the required clinical training and the types of facilities approved to provide the clinical training. Subsection (d)(10) of Section 2089.5 provides that the medical school shall bear the cost of any site inspection that the Division finds necessary to determine if the school's clinical training program complies with this subdivision.

In reference to the Division's authority to approve medical schools, Section 1314 of Title 16 of the California Code of Regulations provides that those medical schools accredited by the Liaison Committee on Medical Education (LCME) are deemed to be approved by the Division. The LCME accredits medical schools located in the United States and Canada. No agency accredits international medical schools worldwide. Therefore, the Division's approval efforts apply to medical schools located outside the United States and Canada.

Many of the developed world's medical schools were founded hundreds of years ago. Their mission, and the mission of most international medical schools, is to train physicians to address the medical needs of their country's population. Before 1986, when a graduate of a new or unfamiliar medical school applied for licensure, the Division of Licensing relied on the information provided on an applicant's medical school transcript and the Board's A Certificate of Medical Education® form, signed and sealed by the medical school's dean, to determine whether the medical school was providing an education that complied with the requirements in Section 2089.

In the late 1970s, a new type of medical school developed in the Caribbean area. Entrepreneurs began to open for-profit, proprietary medical schools in the Caribbean and Dominican Republic aimed at attracting American citizens who were unable to gain acceptance

into U.S. medical schools. These medical schools were popularly referred to as Aoffshore® schools. Previously, most American citizens who had been rejected by U.S. medical schools would attend established medical schools in Mexico, Europe and elsewhere where it may take five, six or seven years to complete the curriculum, and it was necessary to learn a foreign language. The offshore schools offer English-language instruction in a four-year format or less. Students complete basic sciences coursework on the island. Because most islands have no teaching hospitals, the students then complete their clinical training in hospitals located in other countries.

In the spring of 1983, U.S. Postal Service investigators uncovered evidence of the widespread production of fraudulent medical diplomas and other unethical practices on the part of officials at two medical schools in the Dominican Republic that catered to U.S. citizens. These schools were known as CETEC University and CIFAS University. During the course of their investigation, other medical schools in the Dominican Republic and Caribbean were implicated. The Medical Board of California formed a task force to investigate the extent of fraudulent documentation that graduates of offshore schools may have submitted to the Board. The Board's investigators confirmed that offshore school officials had submitted bogus documents to this Board on behalf of their graduates and had violated Section 1327 of Title 16 of the regulations. At least 15 hospitals in California were unlawfully training offshore students in clinical clerkships. In many cases, students received little or no supervision or evaluation. Most of the participating hospitals were small community hospitals that lacked the trained faculty, broad patient census and other resources needed to support a clinical training program for medical students. It was clear that the medical education being provided unlawfully in these hospitals did not comply with statute.

As a result of the U.S. Postal Service's investigation, the Division of Licensing disapproved CETEC University on May 19, 1983. Effective October 11, 1984, the Division temporarily disapproved six other medical schools in the region, including CIFAS University. Pursuant to the authority in Sections 2084 and 2089, the Division began to individually review new medical schools in the Caribbean to determine if they had the resources to effectively provide the curriculum required in statute. In conducting these reviews, the Division members followed general LCME guidelines and used the assistance of expert medical educators from California medical schools. The Division identified many deficiencies in the curriculums, resources and facilities. The schools' problems were exacerbated by the fact that student tuition is their only source of revenue. Some typical deficiencies included frequent turnover of faculty, inadequate numbers of qualified, experienced faculty, poor to non-existent laboratory and library resources, lack of research opportunities for students and faculty, lack of coordination between basic sciences and clinical sciences faculty, who were often in separate countries, loose admissions standards, and inadequate student support services. The Division disapproved the most severely deficient schools and directed schools with less serious deficiencies to bring their programs into compliance with reasonable standards. To address the problem of the geographical separation of clinical facilities from the schools' campus, the Division also sponsored legislation (Section 2089.5 in the Statutes of 1985, Chapter 1178) to strengthen the clinical training requirements. These amendments were intended to protect the interests of medical students and the patients they will treat during their clinical training.

For reference purposes, included in the Underlying Data is a copy of a July 1996 report prepared after the Division conducted site inspections of three medical schools in the Dominican Republic, known as UTESA, UNIREMHOS and INTEC. Following the Division's consideration of this report, the Division voted to grant recognition to INTEC and disapprove UTESA and UNIREMHOS. The report illustrates how the Division applied the more universal

elements of LCME-s standards to the review of these Dominican schools while allowing for cultural factors unique to the country.

Over the past 20 years, the Division has conducted individual reviews of several international medical schools to determine their compliance with the minimum requirements in Sections 2089 and 2089.5 of the Business and Professions (B&P) Code. The Division has followed a standard process in reviewing these schools. However, the review process has not been adopted in regulations. Adoption of the draft regulations will rectify this deficiency and allow the Division to notify consumers and international medical school administrators of the minimum standards expected of medical schools whose graduates wish to apply for licensure in California. In the attached regulatory amendments, the Division proposes to add additional definitions to Section 1300.4, such as *Acriculum*® and *Asemester unit*.® This will ensure that the Division and medical educators are interpreting these terms consistently.

To augment Section 1314 of the regulations, the Division proposes to add a new section, 1314.1, to outline its process and standards for reviewing international medical schools.

Subsection (a) of Section 1314.1 will explain which types of medical schools are subject to the Division-s intensive review process. There are over 1,000 medical schools in 157 countries around the world. The vast majority satisfy the criteria in subsection (a)(1) and will not be subject to the review process outlined in subsection (b). However, subsection (h) will allow the Division to reevaluate any institution in subsection (a)(1) if the Division receives credible information suggesting that the institution may no longer be in compliance with statute. Specific events that might trigger a reevaluation would include reports of medical schools closed, destroyed or relocated due to cataclysmic natural disasters or war.

Medical schools that do not satisfy the criteria in subsection (a)(1) of Section 1314.1 will need to demonstrate that they meet the standards in subsection (b). Subsection (b) will require the institution to have a clearly-stated written mission and objectives that are consistent with preparing graduates to provide competent medical care. In reviewing medical schools, the Division will use these as a reference point for determining if schools have adequate resources to provide the medical education program required in Section 2089 as well as carry out their stated mission and objectives. The other elements that the Division will scrutinize during its review are the institution-s organizational structure, curriculum, governance, faculty, admission and promotion standards, financial resources, facilities, quality assurance system and record-keeping system. All of these elements reflect the LCME-s standards for medical school accreditation and have proved to be important elements in the Division-s prior medical school reviews. Subsections (b)(2) through (b)(10) will delineate the Division-s expectations in these areas. The proposed regulations do not rigidly quantify each standard (for example, by establishing a minimum faculty-to-student ratio) because medical schools differ from country to country in their size, enrollment and technological resources. However, the standard that the Division will apply is whether the medical schools are complying with their stated mission and objectives. The final subsection (b)(11) requires a level of institutional oversight between the main campus and any branch campus that it operates. This will protect the interests of students who are training outside the institution-s main campus.

Subsection (c) grants the Division the discretion to determine if a site inspection is necessary to determine if the medical education program is in compliance with regulation. As stated above, the Division does not intend to evaluate and visit every medical school in the world but will identify those schools that meet the criteria for review. Generally, those will be schools that do not satisfy the criteria in subsection (a)(1) of Section 1314.1 and are structured similarly to schools that the Division has found to be non-compliant in the past.

Subsection (d) confirms that the Division has the authority to disapprove a medical school that fails to provide requested data regarding its educational program or cooperate with a site team.

The Division has exercised this authority twice to disapprove uncooperative medical schools that sought to block the Division's review of their program by refusing to release detailed information regarding their facilities and resources. The Division provided both schools with due process prior to and after the disapproval action.

Subsection (e) outlines the process for conducting site inspections to international medical schools. This process reflects the Division's past experiences, codifies past practices, and provides adequate time and opportunity for the medical school to respond to the site inspection team's report and correct any errors of fact before the Division reviews and acts upon the report.

Subsection (f) will require international schools to notify the Division of any change in their location, mission, name, curriculum or a shift in control that would affect their compliance with statute. At the Division members' request, this subsection includes a provision requiring previously-recognized medical schools to be reevaluated every seven years to determine their continued compliance with statute.

Subsection (g) will require the Division or its designee to review the documentation that certain medical schools may be required to submit every seven years and determine whether the medical school remains in compliance with Sections 2089 and 2089.5 of the code.

If the Division finds it necessary to withdraw a medical school's recognition because the institution no longer complies with statute, subsection (h) will require the Division to notify the institution in writing of its intent to withdraw its recognition and the deficiencies on which the action is based. The institution will have 120 days from the date of the notice to respond to the Division's allegations.

As stated previously, subsection (i) will grant the Division the discretion to evaluate any institution identified in subsection (a)(1) if the Division has reason to believe that the institution may no longer be in compliance with statute. The Division's evaluation might be triggered by news of major changes in a school's curriculum or a medical school's destruction or relocation due to a natural disaster or war. This provision will balance the Division's focus on institutions that need to be reviewed under subsection (b).

### **Underlying Data**

The Division of Licensing's process for reviewing international medical schools is based on the process and standards employed by the Liaison Committee on Medical Education (LCME) to review U.S. and Canadian medical schools. The LCME's publication, *Functions and Structure of a Medical School*,<sup>6</sup> describes the LCME's standards for accrediting medical education programs. This publication is available on the LCME's web site at: [www.lcme.org](http://www.lcme.org). In drafting the proposed regulations, legal counsel relied on hands-on experience gained during prior site inspections of international medical schools. The Division invited input from affected parties and took testimony from the public during several public meetings. The Board mailed meeting agendas to all persons on the Board's mailing list and noticed the meetings on the Medical Board's web site.

The first draft of the proposed regulations was made public during the Division's May 2002 Division meeting. On July 16, 2002, the Division invited all interested parties to participate in a workshop in Sacramento. Participants included attorneys for three Caribbean medical schools that the Division has visited several times. The regulations were amended and presented to the Division and the public again at meetings held on July 24, 2002, November 7, 2002, January 30, 2003 and January 31, 2003. For reference, the minutes from these meetings were used as part of the underlying data. Copies of the minutes are in the rulemaking file. The current draft of the regulations represents testimony obtained during these six public meetings. All relevant testimony and suggested amendments have been considered. Legal counsel eliminated suggested amendments that would not be compatible with California's regulatory scheme and incorporated the most relevant suggestions into the proposed draft regulations.

Also used as part of the underlying data was the July 1996 report following the Division's site inspection of three medical schools in the Dominican Republic. This report is available in the rulemaking file.

### **Business Impact**

This regulation will not have a significant adverse economic impact on businesses.

### **Specific Technologies or Equipment**

This regulation does not mandate the use of specific technologies or equipment.

### **Consideration of Alternatives**

No reasonable alternative which was considered or that has otherwise been identified and brought to the attention of the board/bureau/commission/program would be either more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons than the proposed regulation.

Set forth below are the alternatives which were considered and the reasons each alternative was rejected:

The alternative to this proposal is to not adopt regulations; that is, for the Division to continue reviewing international medical schools using its existing methodology, which has proved successful in separating adequate from inadequate schools. However, this would leave the Division vulnerable if an international medical school were to challenge its disapproval in court. School officials could charge that the Division enforces unpublished standards that constitute *underground regulations* and/or that the Division abuses its authority by inconsistently applying unpublished standards from school to school.